

**Department of Veterans Affairs
Office of Research and Development
Clinical Science Research and Development Service
Minutes of the Cooperative Studies Scientific Evaluation Committee (CSSEC)**

The meeting was held at the Jurys Washington Hotel, Washington, DC on Tuesday, June 17, 2008. The Chairperson, George Machiedo, MD, presided.

CSSMRB members present

George Machiedo, MD - Chair
Warren Browner, MD, MPH
Barry Davis, MD, PhD
Michael Domanski, MD

Theodore Karrison, PhD
Sheryl F. Kelsey, PhD
Karl Kieburtz, MD, MPH (via teleconference)

Other attendees

Ronald Goldberg, M.D.
Mitchell Magee, M.D.
Laura Mauri, M.D., MSc
Susan Sonne, Pharm.D. (via teleconference)
CSP study proponents (see attached agenda)

Donna W. Cain, B.A.
Heather M. Campbell, Pharm.D.
Mike R. Sather, Ph.D., FASHP

VACO ORD Staff present:

Timothy O'Leary, MD, PhD
Grant Huang, MPH, PhD
Bridgett Baer
Kelli Potter

Dr. Timothy O'Leary, Director, Clinical Science Research & Development Service and Dr. Grant Huang, Deputy Director, Cooperative Studies Program (CSP), opened the General Session of the Cooperative Studies Scientific Evaluation Committee (CSSEC) at 8:30 AM. Participants were welcomed and thanked for contributing their expertise in reviewing the proposals. Comments were made that the strength of CSP research is because of the strong review process that CSSEC provides. Introductions of attendees were then made. Dr. O'Leary then proceeded with providing a program update. Key points included:

1) The Committee's charter has been renewed. The committee name has been revised to more accurately reflect the committee's scope and to acknowledge its established history in clinical trials research for VA.

2) A CSSEC subcommittee has been established to review genetic epidemiology proposals for CSP. Scientific review by this subcommittee will help advance the genomic medicine efforts conducted by the program. It will also enable a centralized process that is coordinated with program priorities and policies.

3) Some CSP studies have received attention in the media recently. These studies are:

- CSP 530, "Intensive vs. Conventional Renal Support in Acute-Renal Failure" which was published in the May 2008 on-line edition of the New England Journal of Medicine.
- CSP #565, "The VA Diabetes Trial", which had results presented at the American Diabetes Association Annual Meeting earlier this month.
- CSP #519, which is an on-going strategy trial looking at ways to help veterans with PTSD stop smoking was the subject of a newspaper report. Unfortunately, the report was misleading and inaccurate and VA is working to address these points.

4) New studies that are in planning include one that will evaluate a brain-computer interface and its ability to enhance communication capabilities among patients with Amyotrophic Lateral Sclerosis. Another study that is still under discussion may involve examining a prosthetic arm. CSP also has two clinical trials in pneumonia and gastroesophageal reflux disease in planning.

5) There was an increase in the research budget for FY 08. This increase will help with VA's ability to research healthcare issues for veterans returning from Iraq and Afghanistan in addition to topics affecting veterans throughout the VA healthcare system.

6) There are a number of CSP initiatives underway including:

- efforts to standardize the IT infrastructure within the CSP Coordinating Centers;
- the establishment of a Board of Directors within CSP consisting of CSP Coordinating Center Directors to help with providing direction and executing major program initiatives;
- discussions on possibly establishing "nodes" at VA medical centers that would be specifically focused and dedicated to conducting CSP studies

7) Finally, VA is establishing a Central IRB that has held organizational meetings in recent months. The Central IRB will review all new CSP studies and it is expected that they will be a significant part of the overall process for reviewing CSP studies. A CSP study is expected to be the first study that will be reviewed by this group.

The study review portion of the meeting was begun with Dr. Machiedo explaining the review process: the reviewers would meet in a closed session and give brief synopses of their comments on the proposals before the Committee; study teams (proponents) are then brought in to make brief presentations to the Committee; proponents are apprised of reviewer comments by Dr. Huang; and an interactive discussion with the CSSEC follows. An Executive Session with only CSSEC members follows to discuss recommendations for the study and to score it.

Committee members were informed that the proceedings and recommendations pertaining to the review of research proposals are considered to be privileged and confidential information. They were also asked to indicate any conflict of interest that may not have been identified prior to the meeting.

The review portion of the meeting progressed as scheduled. There were two new studies and two midterm/extension request reviewed at the meeting.

New Submissions:

CSP #570 "Hospitalized Patients with a Non-Cardiac Concomitant Illness and an Elevated Cardiac Troponin: Early vs. Deferred Intervention Tactic (EDIT) Trial"

CSP #571 "Drug-eluting Stents vs. Bare Metal Stents In Saphenous Vein Graft Angioplasty (DIVA) Trial"

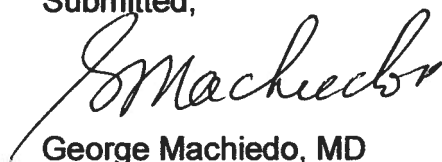
Midterm/Extension Review:

CSP #504 "Risperidone Treatment for Military Service Related Chronic Post – Traumatic Stress Disorder"

CSP #557 "VA Coronary Artery Revascularization in Diabetes Study (VA CARDS)"

The next meeting was proposed to be held in late 2008. CSP Central Office staff will contact CSSEC members to determine their schedules and coordinate the next meeting. The meeting concluded at 3:00 PM on June 17, 2008.

Submitted,

A handwritten signature in black ink, appearing to read "G Machiedo", written over the printed name.

George Machiedo, MD
Chair CSSEC